

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEBRASKA**

**RALPH SELL, individually and as  
personal representative of the ESTATE  
OF ALICE SELL,**

**Plaintiff,**

**vs.**

**BAXTER HEALTHCARE  
CORPORATION, a Delaware  
corporation, BAXTER  
INTERNATIONAL, L INC., a  
Delaware corporation, AM2PAT, INC.  
a/k/a/ SIERRA PREFILLED, INC. an  
Illinois corporation, and B. BRAUN  
MEDICAL, INC., a Pennsylvania  
corporation,,**

**Defendants.**

**4:09-CV-3036**

**AMENDED ANSWER OF  
DEFENDANT  
B. BRAUN MEDICAL, INC. TO  
AMENDED COMPLAINT**

COMES NOW this answering Defendant and for its Amended Answer and Affirmative  
Defenses to the Amended Complaint alleges:

**AMENDED ANSWER**

1. Denies the allegations set forth in paragraph 1 of the Amended Complaint for the  
reason that NEB. REV. STAT. § 25-21,180 does not guarantee any rights.

2. This Defendant is without sufficient information to admit or deny paragraphs 2, 3  
and 4 of the Amended Complaint and therefore denies the same.

3. This Defendant admits the allegations of paragraphs 5, 6, 7 and 8 of the Amended Complaint.

4. This Defendant admits the allegations contained in paragraph 9 of the Amended Complaint that it is a for-profit corporation with its principle place of business in the Commonwealth of Pennsylvania.

5. This Defendant denies the allegations contained in paragraphs 10, 11, 12, 13 and 15 of the Amended Complaint.

6. This Defendant is without sufficient information to either admit or deny the allegations contained in paragraphs 14 and 16 (including sub-parts) of the Amended Complaint and therefore denies the same.

7. As to the FIRST CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, and 29 (including sub-parts) except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

8. As to the SECOND CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, and 42 (including sub-parts) except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

9. As to the THIRD CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 43, 44, 45, 46, 47, 48, 49, and 50 except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

10. As to the FOURTH CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 51, 52, 53, 54, and 55 (including the sub-parts) except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

11. As to the FIFTH CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 56, 57, 58, 59, and 60 except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

12. As to the SIXTH CLAIM FOR RELIEF of the Amended Complaint, this Defendant denies the allegations contained in paragraphs 61 and 62 except to the extent that it previously admitted all or parts 1 through 16 that are incorporated by reference into this claim for relief in the Amended Complaint.

#### **AFFIRMATIVE DEFENSES**

13. FIRST DEFENSE: Plaintiff has failed to state a claim upon which relief may be granted.

14. SECOND DEFENSE: Any of this Defendant's products, as alleged in the Amended Complaint, were in conformity with the generally recognized and prevailing state of the art in the industry at the time the specific product(s) involved in the action was first sold to any person not engaged in the business of selling such product(s) and no practical and technically feasible alternative formulation was available that would have prevented the harm for which plaintiff seeks to recover without substantially impairing the safety, efficacy, or usefulness of the product for its intended use.

15. THIRD DEFENSE: To the extent any of this Defendant's products as alleged in the Amended Complaint, may have been altered prior to their delivery to the user, this Defendant is not legally responsible.

16. FOURTH DEFENSE: If the Plaintiff suffered damages as a proximate result of any condition of a product manufactured, distributed, or sold by this Defendant, which this Defendant denies, then as to any such product supplied to any alleged medical care provider of Plaintiff's decedent, such alleged medical care provider was knowledgeable and sophisticated user and/or learned intermediary of said products with adequate warnings or instructions, or with the knowledge of such information contained in the warnings; therefore, this Defendant has no further legal duty to warn or instruct the Plaintiffs.

17. FIFTH DEFENSE: The alleged injuries and/or damages of Plaintiff, if any, are the result of the negligent acts or admissions of other persons, firms, corporations, or entities for which this Defendant is not legally responsible, and which jointly or singularly are the sole

proximate, producing, superseding, intervening, or other cause of all or part of the alleged injuries and damages for which the Plaintiff seeks recovery.

18. SIXTH DEFENSE: The alleged injuries and/or damages of Plaintiff, if any, were not caused by the negligence of this Defendant, but rather were proximately caused by the abnormal, unforeseeable, and/or unintended use and/or misuse of the products in question.

19. SEVENTH DEFENSE: Plaintiff's claims are barred, in whole or in part, because this Defendant acted in good faith at all relevant times and gave adequate warnings of all known or reasonably knowable risks associated with the use of its product.

20. EIGHTH DEFENSE: To the extent that the Plaintiff alleges that the products at issue were marketed, sold, supplied, or distributed by this Defendant, which allegations this Defendant denies, this Defendant was discharged of any duty to warn by providing warnings to the Plaintiff's decedent's medical care providers that were adequate in light of the anticipated user's knowledge of the products used.

21. NINTH DEFENSE: The alleged injuries and/or damages of Plaintiff, if any, were caused by a pre-existing or subsequent medical condition, disease, or illness of Plaintiff's decedent that was unrelated to any product marketed, sold, supplied, or distributed by this Defendant.

22. TENTH DEFENSE: The alleged injuries and/or damages of Plaintiff, if any, were not caused by the negligence of any party, but rather were the result of an unavoidable accident for which this Defendant is not responsible.

23. ELEVENTH DEFENSE: The Plaintiff's claims are barred, in whole or in part, by the lack of any defect, as any products allegedly marketed, sold, supplied, or distributed by this Defendant were marketed, sold, supplied, or distributed in accordance with applicable standard of care and in compliance with all applicable Federal and State statutes and regulations that existed at the time of sale and the prescribed standards for labeling, packaging, warning, or instructions for the use of the product or products allegedly marketed, sold, supplied, or distributed by this Defendant.

24. TWELFTH DEFENSE: If a duty to warn is found to have existed, the same being expressly denied, then this Defendant provided all required warnings regarding its products to the entities to which this Defendant sold its products and to people who used the products and if the Plaintiff's decedent or her medical care providers did not receive these warnings, it was because the products were supplied in bulk and/or the people to whom Defendant's sold its products or the people who used its products did not, through their acts or omissions, pass the warnings along to the Plaintiff's decedent and/or her medical care providers all without any fault on the part of this Defendant.

25. THIRTEENTH DEFENSE: The Plaintiff's decedent was not a foreseeable user of the product at issue.

26. FOURTEENTH DEFENSE: Any damages claimed by the Plaintiff against this Defendant were caused by intervening acts and/or omissions of third parties.

27. FIFTEENTH DEFENSE: The conditions or risks, if any, were known to the Plaintiff and Plaintiff's decedent and were open, obvious, and apparent to them and each of them and they assumed the risk of any alleged injuries or damages arising out of the actual occurrence alleged in the Amended Complaint.

28. SIXTEENTH DEFENSE: The alleged injuries and/or damages of Plaintiff, if any, are in no way related to any alleged use of this Defendant's products. The damages of Plaintiff's were caused or aggravated by other causes or instrumentalities and are not related to any use of this Defendant's products.

29. SEVENTEENTH DEFENSE: The Plaintiff's causes of action are barred because a reasonable user would have been aware of the alleged risk of the product at issue and because the Plaintiffs knew of the alleged risks of the products at issue.

30. EIGHTEENTH DEFENSE: Plaintiff's claims are barred, in whole or in part, because this Defendant did not supply Plaintiff's decedent or her medical care providers with the product or products Plaintiff alleges caused injuries or damages.

31. NINETEENTH DEFENSE: Plaintiff's claims are barred, in whole or in part, because Plaintiff failed to join parties and those persons or entities are necessary to this action and complete resolution of this action cannot be made without the presence of those parties.

32. TWENTIETH DEFENSE: Plaintiff's claims are barred, in whole or in part, because any alleged damages were not caused by any failure to warn on the part of this Defendant.

33. TWENTY-FIRST DEFENSE: This Defendant gives notice that it intends to rely upon any other defenses that may become available or appear during the discovery proceedings in this case and hereby reserves its right to amend the defenses offered in response to Plaintiff's claims.

34. TWENTY-SECOND DEFENSE: Any products supplied to Plaintiff's decedent or to her alleged medical care providers, were at all times reasonably fit and suitable for the purposes for which they were distributed and sold, and the alleged injuries or damages of Plaintiff did not result from any alleged exposure to this Defendant's products, by way of design or marketing defect.

35. TWENTY-THIRD DEFENSE: Plaintiff's claims are barred, in whole or in part, by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States because this Defendant's product, as alleged in the Amended Complaint, is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), and regulations promulgated thereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with specific determinations by FDA specifying the language that should or should not be used in the labeling accompanying the product.



36. TWENTY-FOURTH DEFENSE: Plaintiff's claims are preempted by applicable federal and/or state statutes, rules, standards or regulations.

37. TWENTY-FIFTH DEFENSE: This Defendant did not breach any implied warranties or any warranties created by law.

38. TWENTY-SIXTH DEFENSE: To the extent that Plaintiff claims that this Defendant breached a warranty of merchantability as to any product, Plaintiff and/or Plaintiff's decedent failed to provide this Defendant with timely notice of any alleged breach.

39. TWENTY-SEVENTH DEFENSE: At all times and places in the Amended Complaint, neither Plaintiff nor Plaintiff's decedent were in privity of contract with this Defendant and this lack of privity bars Plaintiff's recovery herein upon any theory of warranty.

40. TWENTY-EIGHTH DEFENSE: As to any unnumbered paragraphs in Plaintiff's Amended Complaint, this Defendant denies the allegations contained therein.

41. TWENTY-NINTH DEFENSE: In further answering, this Defendant denies all other portions of the Amended Complaint except for those allegations specifically admitted herein.

42. THIRTIETH DEFENSE: In further answering, this Defendant denies the nature and extent of Plaintiff's alleged damages.

43. THIRTY-FIRST DEFENSE: In further answering, this Defendant denies any act of alleged commission or omission on the part of this Defendant in the Amended Complaint and denies that this Defendant was the proximate cause of any damages to Plaintiff.

44. Incorporates by reference any additional defenses interposed by any other defendant herein to the extent such defenses are applicable to this Defendant.

WHEREFORE, the Defendant prays that the Amended Complaint be dismissed with prejudice and that this Defendant recover its costs herein expended.

DATED this 27<sup>th</sup> day of April, 2009.

**DEMAND FOR JURY TRIAL**

COMES NOW this answering Defendant and hereby demands trial by jury in this matter in Lincoln, Lancaster County, Nebraska.

B. BRAUN MEDICAL, INC.

BY: Baylor, Evnen, Curtiss, Gruit & Witt, LLP  
1248 O St., Ste. 600  
Lincoln, NE 68508-1499  
(402) 475-1075

BY: \_\_\_\_\_/s/ Walter E. Zink\_\_\_\_\_  
Walter E. Zink II, #14699  
Andrea D. Snowden, #21784

**CERTIFICATE OF SERVICE**

I hereby certify that on the 27th day of April, 2009, I electronically filed the foregoing document with the Clerk of the U.S. District Court using the CM/ECF system which sent notification of such filing to the following:

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Derek A. Aldridge  
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\_\_\_\_\_/s/ Walter E. Zink\_\_\_\_\_  
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